

PATENT COOPERATION TREATY
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 05 OCT 2004

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Applicant's or agent's file reference 12252560/DH	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000779	International Filing Date (day/month/year) 20 June 2003	Priority Date (day/month/year) 20 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁷ G01N 1/31, 35/00, G02B 21/34		
Applicant VISION BIOSYSTEMS LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 29 October 2003	Date of completion of the report 27 September 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer RAJEEV DESHMUKH Telephone No. (02) 6283 2145

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 4-29, 35-36

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 4-29, 35-36

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

Please see the Supplemental Box regarding the lack of unity of invention.

As only some of the required additional search fees were timely paid by the applicant, the International Search Report covers only those claims for which fees were paid, specifically the following claims Nos.:

- (1) Claims 1, 30 and 40 - which have a common feature of wicking means to selectively drain fluid from a slide or reaction chamber, and claims dependent on these claims;
- (2) Claims 37, 41, 42, 45, 47, 51 - which have a common feature of a tray to allow for batch processing, and claims dependent on these claims; and,
- (3) Claims 52 and 53 - relating to a pipette mixing apparatus and method, and claims dependent on these claims.

This International Preliminary Examination Report deals only with the claims enumerated above.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-3, 30-34, 37-53

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-3, 30-34, 37-53	YES
	Claims	NO
Inventive step (IS)	Claims 1-3, 30-34, 37-53	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-3, 30-34, 37-53	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

US 4731335 A (BRIGATI) 15 March 1988—Column 17, lines 36-39. BRIGATI discloses an absorbent material for removing the liquid reagent.

WO 01/04634 A1 (ANGROS) 18 January 2001—Page 16, lines 7-8. ANGROS uses an air pressure nozzle to clear away a rinse buffer.

US 5985669 A (PALANDER) 16 November 1999—Column 5, lines 14-22. PALANDER discloses using a vacuum nozzle and further treatment liquid to replace the current treatment liquid.

US 5595707 A (COPELAND et al.) 21 January 1997—Whole document. COPELAND discloses a carousel slide support.

US 5573727 A (KEEFE) 12 November 1996—Whole document. KEEFE discloses slide racks each containing a plurality of individual slides.

US 6337490 B1 (FURUSATO et al.) 8 January 2002—Whole document. FURUSATO discloses a reciprocating mechanism for simultaneously transferring a plurality of test pieces in a transfer direction.

EP 1174702 A1 (MEDIC SRL) 23 January 2002—Whole document. MEDIC SRL discloses an automatic equipment for processing microscope slides including a slide holding tray.

WO 01/40760 A1 (ACTIVE BIOTECH AB) 7 June 2001—Whole document. ACTIVE BIOTECH AB discloses a system for handling and processing tissue section samples comprising a tray for carrying microscopic slides.

US 6070476 A (SHINE et al.) 6 June 2000—Whole document. SHINE discloses a fluid delivery apparatus comprising two or more delivery syringes.

US 6180061 B1 (BOGEN et al.) 30 January 2001—Whole document. BOGEN discloses a cartridge pump and dispensing assembly for a moving platform slide stainer with heating elements.

None of the cited documents discloses or (individually or in an obvious combination) suggests the invention as claimed in the above Claims, as far as their scope can be construed in light of the detailed description. (The Claims, by themselves, are defined in such sweeping terms that it is difficult to ascertain their scope from the language of the Claims alone.) Therefore the claimed invention is novel, involves an inventive step, and is industrially applicable, subject to the Observations made under Box VIII.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The description from page 28, line 17 to page 30, line 19—drafted like Claims—is not clear.
2. The technical features of the invention(s) are not clear due to the multiplicity of independent claims. Even within the groups of Claims that, according to the applicant, define one invention, there are numerous independent claims without a common general inventive concept.
3. The applicant was invited to insert—into the description—references to the prior art cited in the International Search Report and to discuss the relation in relation to these references so as to put the invention into proper perspective.
4. The Claims are not fully supported by the description because they are not limited to the field of the invention, i.e. microscopic slides. The claims use vague and indeterminate terms like "substrate".
5. Claims are not clear because they seek to define the invention by a result to be achieved rather than by means of positive features that achieve that result. For example, Claims 1, 30 and 40 attempt to define the draining mechanism as including "wicking means", but does not define how wicking is achieved—there is no wick or an absorbent material disclosed in the specification.
6. The Claims are not clear because they use vague terms like "wicking posts" which would have no clear meaning for a person skilled in the art.
7. According to the applicant, Claims 37, 41, 42, 45, 47, 51 have a common feature of "a tray to allow for batch processing"—however this common feature is clearly not novel in light of the cited art. Consequently these claims are not so related so as to form a common general inventive concept.
8. Claims 52 and 53 are drafted as independent claims. This leads to uncertainty as to which technical features are sought to be protected and as to which technical features define the invention.
9. Overall the description is quite specific, but the claims are couched in such broad terms that it is difficult to interpret the scope of the claims from the words of the claims alone.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box IV

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). The requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features (i.e. those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art). The present application has 16 independent claims. The lack of unity is manifestly obvious from the wording of these claims below:

Claim 1. A biological reaction apparatus for receiving at least one substrate having a sample located in a sample region, and a separate cover, such that a reaction chamber is formed between the cover and substrate over the sample region, wherein the apparatus includes a locating means to locate the substrate; a cover locating means for locating and moving the cover with respect to the substrate; a fluid dispensing means for dispensing fluid into the reaction chamber; and a draining mechanism; wherein the draining mechanism includes wicking means.

Claim 4. A fill fluid for performing a filling of a reaction chamber, where the fill fluid has a viscosity higher than an antecedent fluid on a substrate.

Claim 16. A receptacle for substrates having receiving means adapted to locate a substrate and a cover.

Claim 24. A dispenser for a reaction apparatus including a fluid conduit, a pump connected to the fluid conduit; a locating means for moving the fluid conduit from a fluid source to a dispensing region.

Claim 28. A method of dispensing fluid to a substrate including the steps of: loading a reagent receptacle with at least one fluid container; mounting the reagent receptacle to a reaction apparatus detecting the reagent receptacle once the reagent receptacle is detected, initiating a sensor to detect the type of fluid within the at least one fluid container, storing the information on fluid type to allow the fluid to be dispensed onto a substrate when required.

Claim 30. A reaction apparatus having a support projection for a slide, a dispensing means and a fluid removal means, where the a support projection is adapted to support a slide from underneath, and a wicking means contacting the periphery of the slide, such that the wicking means provides a wicking path to remove fluid from the upper surface of the slide.

Claim 35. A reaction apparatus adapted to locate a substrate having a surface containing a sample and cover having a surface forming a reaction chamber with the sample containing surface, including a cover engaging means adapted to change the volume of the reaction chamber.

Claim 37. A reaction apparatus having a separate substrate tray: the substrate tray adapted to hold number of substrates and covers; at least one receiving station for receiving said substrate tray; a dispensing means for dispensing fluid onto substrates in the substrate tray wherein a reaction chamber is formed between the substrate and cover, such that fluid dispensed onto the substrates enters the reaction chamber.

Claim 40. A reaction apparatus for receiving a substrate having a sample located in a sample region and a draining mechanism including wicking means for draining fluid from the substrate.

Claim 41. A method of forming a reaction chamber on a slide in a reaction apparatus including: placing a cover having a cavity on a slide, forming a reaction chamber; locating the cover and slide in a receptacle of a tray; providing a receiving portion in the reaction apparatus having a mount for each receptacle in the tray; loading the tray into a receiving portion of the reaction apparatus, where the receiving portion of the reaction apparatus locates the tray; releasably holding the cover to the slide; and releasing the tray from the slide and cover.